

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO: Wave 5 & 6 Cases	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**DEFENDANTS' MEMORANDUM OF LAW
IN SUPPORT OF MOTION FOR SANCTIONS**

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon"), by counsel, hereby move pursuant to Federal Rule of Civil Procedure 37 for sanctions based on Plaintiffs' failure to comply with the Court's September 26, 2017 Order ("9/26/2017 Order"), including (i) the exclusion of any opinions offered by Dr. Scott Guelcher based on A. Talley, *et al.*, "Oxidation and degradation of polypropylene transvaginal mesh," J. Biomater. Sci., Polymer Ed. (2017); (ii) an award of the reasonable expenses incurred by Ethicon as a result of Plaintiffs' failure to comply with the 9/26/2017 Order; (iii) instructions that Plaintiffs comply with this Court's 9/26/2017 Order within 10 days of entry of a new order; and (iv) any other relief deemed appropriate by this Court.

BACKGROUND

This Motion arises from Plaintiffs' failure to comply with an order issued by this Court on September 26, 2017. Scott Guelcher, Ph.D. is an expert witness for Plaintiffs in this litigation, including cases in Waves 5 & 6. *See* Ex. A, Wave 5 Expert Witness Disclosure; Ex. B, Wave 6 Expert Witness Disclosure. Following motion practice and a hearing before this Court on August 9, 2017, Ethicon deposed Dr. Guelcher on August 17, 2017 regarding his opinions.

As a part of its August 14, 2017 Second Amended Notice of Deposition, Ethicon requested that Dr. Guelcher bring to the deposition certain documents pertaining to a 2017 paper—A. Talley, *et al.*, “Oxidation and degradation of polypropylene transvaginal mesh,” J. Biomater. Sci., Polymer Ed. (2017)—which forms the basis of certain of his opinions. *See* ECF No. 4323. Plaintiffs objected to Ethicon’s request, (ECF No. 4370), and produced only certain “supplemental data” that had been published with the paper, (Ex. C, T. Jackson 8/16/2017 Email). Plaintiffs did not mention or produce any of the other raw data or documents requested by Ethicon. Ex. C, T. Jackson 8/16/2017 Email. And while Dr. Guelcher conceded at deposition that he could have obtained the requested materials prior to his deposition, he made no effort to do so. *See* Ex. D, Guelcher 8/17/17 Dep. 17:9-20:8, 86:17-87:12.

On September 1, 2017, Ethicon filed a motion to compel the production of the requested materials. [ECF No. 4582 & 4584] Plaintiffs continued to oppose the production of those materials. [ECF No. 4673]

Following a telephonic hearing on Ethicon’s motion to compel, the Court entered an order requiring Plaintiffs to produce certain of the requested materials. *See* 9/26/2017 Order; *see also* Ex. E, 9/26/2017 Hearing Tr. at 5:17-6:2. Specifically, the Court ordered Plaintiffs to produce the following materials in connection with the Talley paper: (i) protocols; (ii) raw data; (iii) information about specimens and materials; (iv) images, such as photographs, taken during the collection of data (collectively, the “Ordered Production”). *See id.*

Notably, having been ordered to produce these materials, Plaintiffs’ counsel stated that “we will, pursuant to your ruling, act promptly, like today, to uncover exactly where that’s at, what we can get and exactly what he relied on and then we will confer with Mr. Thomas as soon

as possible,” and assured the Court that “we can get this done pretty quickly.” Ex. E, 9/26/2017 Hearing Tr. at 9:17-10:10.

Although Ethicon has repeatedly contacted Plaintiffs regarding the Ordered Production, to date, Plaintiffs have not fully complied with their obligation to produce the required materials. Ex. F, D. Thomas 10/2/2017 Email (requesting information regarding the Ordered Production); Ex. G, D. Thomas 10/12/2017 Email (requesting status as to Ordered Production); Ex. H, D. Thomas 10/18/2017 Email (requesting Ordered Production). Indeed, Plaintiffs failed to produce a single document until October 20, 2017, when they produced a limited set of FTIR data. *See* Ex. I, T. Jackson 10/20/2017 Email (attaching certain FTIR data). At that time, Plaintiffs informed Ethicon that they would “follow up on this with you Tuesday [October 24, 2017.]” *Id.*

But Ethicon did not receive any further communications from Plaintiffs regarding the Ordered Production until October 26, 2017, after Ethicon announced its intention to move for relief based on the clear insufficiency of Plaintiffs’ production and the passage of a month since the entry of the 9/26/2017 Order. *See* Ex. J, D. Thomas 10/26/2017 Email. Even then, however, Plaintiffs indicated that they had no intention of making a further production. *See id.* Indeed, Plaintiffs informed Ethicon’s counsel that he should have “reach[ed] out” to Plaintiffs again “if you are not satisfied with what you have[.]” *Id.*

Ethicon directed Plaintiffs to both the scope of their obligation under the 9/26/2017 Order, and their own assurances regarding the timing of the production. *Id.* Plaintiffs subsequently informed Ethicon that they complied with the 9/26/2017 Order because Dr. Guelcher had informed them that “he had no additional data in his possession which would be responsive to the order[.]” and “Dr. Guelcher has explained that he doesn’t control his co-authors.” Ex. K, T. Jackson 10/29/2017 Email.

Subsequently, on October 31, 2017, Plaintiffs produced certain SEM images that Dr. Guelcher purportedly “did not previously have access to.” Ex. L, T. Jackson 10/31/2017 Email. Once again, Plaintiffs informed Ethicon that they believed they had satisfied their obligations under the 9/26/2017 Order. *Id.*

To date, Plaintiffs have not produced the balance of the raw test data or any protocols, information about specimens and materials, or images taken during the collection of data.

ARGUMENT

I. Legal Standard

Federal Rule of Civil Procedure 37(b) governs situations in which a party fails to comply with a court’s discovery orders. Fed. R. Civ. P. 37(b)(2). Specifically, Rule 37(b) provides that “[i]f a party . . . fails to obey an order to provide or permit discovery, including an order under . . . [Rule] 37(a), the court where the action is pending may issue further just orders” to sanction that party’s non-compliance. *Id.* Available sanctions include, but are not limited to, an order “prohibiting the disobedient party from supporting or opposing designated claims or defenses, or from introducing designated matters in evidence[.]” Fed. R. Civ. P. 37(b)(2)(A)(ii). Further, when a court imposes sanctions under Rule 37(b), it “must order” the payment of “reasonable expenses, including attorney’s fees, caused by the failure, unless the failure was substantially justified” or such an award would be “unjust.” Fed. R. Civ. P. 37(b)(2)(C).

The Fourth Circuit Court of Appeals has identified four factors a district court should consider in determining what sanctions to impose under Rule 37(b):

1. whether the non-complying party acted in bad faith,
2. the amount of prejudice that noncompliance caused the adversary,
3. the need for deterrence of the particular sort of non-compliance, and

4. whether less drastic sanctions would be effective.

Wilson v. Volkswagen of Am., Inc., 561 F.2d 494, 506-07 (4th Cir. 1977); *accord Belk v. Charlotte–Mecklenburg Bd. of Educ.*, 269 F.3d 305, 348 (4th Cir. 2001) (en banc), *cert. denied*, 535 U.S. 986 (2002).

II. Plaintiffs’ Failure to Comply with the Court’s September 26, 2017 Order Warrants Sanctions.

Application of the *Wilson* factors demonstrates that the Court should issue an order precluding Dr. Guelcher from relying on the Talley paper or any of the requested materials at trial; requiring Plaintiffs to comply with the Court’s 9/26/2017 Order within 10 days; and awarding Ethicon’s reasonable expenses arising from Plaintiffs’ failure to do so without Court intervention.

First, Plaintiffs’ failure to comply with the Court’s 9/26/2017 Order is clearly in bad faith. Having been ordered by the Court during the telephonic hearing to produce the requested materials, Plaintiffs’ counsel assured the Court that “we can get this done pretty quickly.” Ex. E, 9/26/2017 Hearing Tr. at 9:17-10:10. Yet, despite repeated attempts by Ethicon to work with Plaintiffs to complete the production, Plaintiffs have failed to comply with the Court’s order by producing the requested materials. Ex. F, D. Thomas 10/2/2017 Email (requesting information regarding the production of the requested materials); Ex. G, D. Thomas 10/12/2017 Email (requesting information regarding progress in production of the requested materials); Ex. H, D. Thomas 10/18/2017 Email (requesting production of requested materials).

Although Plaintiffs eventually produced certain raw data in a limited production on October 20, 2017, (Ex. I, T. Jackson 10/20/2017 Email), and some additional raw data in an October 31, 2017 production, (Ex. L, T. Jackson 10/31/2017), they have not fully complied with their obligations under the 9/26/2017 Order. Indeed, Plaintiffs have still not produced any

protocols, information about specimens and materials, images taken during data collection, or the remainder of the raw test data (including, but not limited to, XPS data).

Turning to the second *Wilson* factor, Ethicon continues to be prejudiced by Plaintiffs' refusal to produce the requested documents and underlying data. Ethicon has filed in Waves 5 and 6 *Daubert* motions to exclude certain of Dr. Guelcher's opinions, including his opinions based upon the 2017 Talley paper. [ECF Nos. 4573, 4584, and 4817] While Ethicon has shown that both the paper and Dr. Guelcher's opinions based on it are methodologically unsound and unreliable, the underlying data is nevertheless important to Ethicon's ability to fully test the paper's reliability.

For example,¹ Plaintiffs have not provided any protocols used by the Talley authors, including but not limited to any protocol followed by Dr. Iakovlev to clean explanted mesh fibers. As discussed in Ethicon's motion to exclude Dr. Guelcher's opinions, the only information in Talley regarding the preparation of the explanted mesh fibers they analyzed is that "the outer layer was mechanically removed using tweezers and a scalpel blade under a dissection microscope." *See* Defs. Mem. of Law in Supp. of Mot. to Exclude the Opinions and Testimony of Scott A. Guelcher, Ph.D. [ECF 4574] ("Guelcher *Daubert* Motion") at 11-12 (quoting Talley at 5).² As Ethicon explained, this general description is not a protocol, and does not identify any objective criteria regarding the authors' methods. *Id.* Without this information, it is impossible to test the Talley authors' work by reproducing it.

Plaintiffs have also failed to produce all of the raw data generated by the Talley authors. For instance, the Talley authors claim that they found evidence of degradation (on an AMS-

¹ By listing some of the materials Plaintiffs have failed to produce and not others, Ethicon is not limiting the information Plaintiffs should produce pursuant to the Court's 9/26/2017 Order.

² Ethicon filed the Guelcher *Daubert* Motion in Wave 5, and adopted it in Wave 6. [ECF 74817]

brand mesh) based on, among other things, X-ray photoelectron spectroscopy (“XPS”). As discussed in Ethicon’s *Daubert* motion, however, the limited sets of XPS data and figures included in the article were riddled with errors and inconsistencies. *See Guelcher Daubert* Motion at 8-11. Although these flaws clearly render the Talley authors’ work unreliable, Ethicon cannot completely assess their analysis without the raw XPS data.

Nor did Plaintiffs produce any information regarding the specimens and materials used in their testing. For example, the authors provided no information regarding their use of a 20% hydrogen peroxide solution for their intentional oxidation testing. This omission is significant because not only did the Talley authors fail to demonstrate that their oxidative medium actually replicates the oxidative environment in the human body, but they inexplicably deviated from the 10% solution used in the article on which their approach was purportedly based. *See Guelcher Daubert* at 5-6.

Similarly, the authors provided no information regarding the mesh explant they analyzed with XPS, such as the selection criteria used by the authors, the duration of implantation, the reason the mesh was removed, the handling of the mesh during implantation, the handling of the mesh during and after explantation, the manner of dry preservation, and so on. This information—as well as all other information regarding the authors’ specimens and materials—is necessary to permit Ethicon to evaluate the Talley authors’ methods.

Furthermore, Ethicon submits that a complete production pursuant to the terms of the Court’s 9/26/2017 Order is needed so that Ethicon can determine whether depositions of Dr. Guelcher’s co-authors are warranted. This information is particularly necessary given Dr. Guelcher’s inability to answer questions regarding the underlying data and testing at deposition. *See Ex. D, Guelcher 8/17/17 Dep.* 44:2-18; 44:25-48:17; 60:4-61:1; 62:5-63:1.

Third, there can be no doubt as to the need to deter non-compliance with the Court's discovery orders, particularly when such non-compliance is unaccompanied by any justification whatsoever.

Fourth, Ethicon submits that less drastic sanctions would not be effective. This Court has already issued a valid, just Order requiring Plaintiffs to produce the requested materials. The issuance of another order reminding Plaintiffs of their obligation to comply with a previously issued order would not only be a waste of judicial resources, but it would invite further non-compliance with the Court's orders.

CONCLUSION

For the reasons discussed above, Ethicon respectfully requests that the Court enter an order imposing sanctions on Plaintiffs based on their failure to comply with the Court's September 26, 2017 Order ("9/26/2017 Order"), including (i) the exclusion of any opinions offered by Dr. Scott Guelcher based on A. Talley, *et al.*, "Oxidation and degradation of polypropylene transvaginal mesh," J. Biomater. Sci., Polymer Ed. (2017); (ii) an award of the reasonable expenses incurred by Ethicon as a result of Plaintiffs' failure to comply with the 9/26/2017 Order; (iii) instructions that Plaintiffs comply with this Court's 9/26/2017 Order within 10 days of entry of a new order; and (iv) any other relief deemed appropriate by this Court.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 13, 2017, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

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